5 February 17, 1998



Regulatory Branch
Division of Programs & Enforcement Policy
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.

Rec'd 2/24/98

Attention:

Consumer Safety Officer

RE:

Promensil™: Statements of Nutritional Support

Ladies/Gentlemen:

Washington, DC 20204

Pursuant to the requirements of the Dietary Supplement and Health Education Act of 1994, this letter is to notify the Food and Drug Administration that our company Novogen, Inc. of 6 Landmark Square, Stamford, Connecticut has in the last 30 days begun marketing its Promensil™ brand dietary supplement of standardized red clover extract containing isoflavone phytoestrogens (daidzein, genistein, biochanin A, formononetin), with the following labeling statements characterizing the mechanism by which such nutrients act to maintain human body structure or function, or describe general well-being from the consumption of these nutrients:

"There is mounting scientific evidence about the importance of isoflavone phytoestrogens (plant estrogens) to human health. Isoflavones, natural plant estrogens, are abundant in legumes such as clover, beans, and soy. They provide a supplement to the bodies own estrogens before, during and after midlife. Promensil is made from red clover, the world's richest source of isoflavones. More than 14 years of research have gone into its development. In a single daily tablet, Promensil provides all four of the important plant estrogens, which the typical American diet lacks. Promensil is particularly recommended as a dietary supplement for women concerned about maintaining healthy estrogen levels to preserve physical and emotional well-being as the body's own estrogen levels decline in midlife"

Sincerely yours,

Warren Lancaster

Vice President - North America

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